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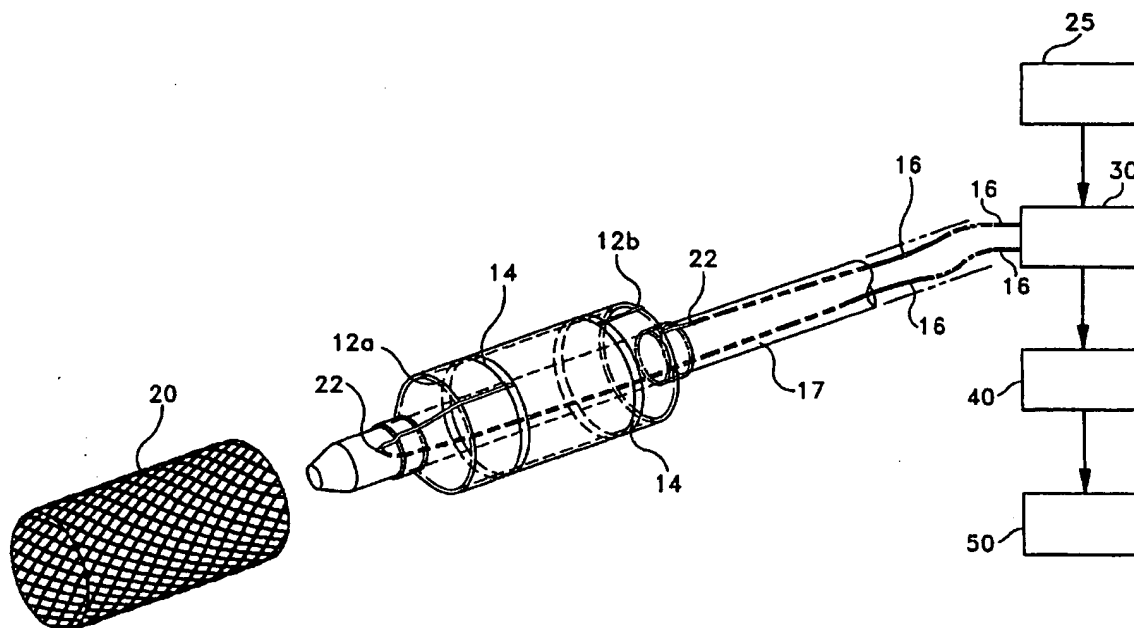
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(54) **Implantable device sensing catheter**

(57) A catheter having a circuit with sensor (14) that provides or communicates a signal relating the location

of a predetermined portion of an elongated tube (17) or balloon (12) relative to an implantable device.

FIG-1



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D ripti n

This invention relates generally to implantable device sensing catheters. Implantable devices such as stents are used in percutaneous transluminal coronary angioplasty and in other medical procedures to repair arteries and body lumens. For example, medical personnel often use a balloon catheter and stent to open a stenosis in an artery. On occasion, stents must be located and replaced due to insertion or dilatation complications.

Manufacturers may provide radiopaque markers on an implantable device to help a physician determine the location of an implantable device in a body lumen. In practice, the cardiologist positions a generally poorly visible stent with readily visible marker bands at the treatment site, deploys the stent, notes the location of the marker bands in relation to an arterial sidebranch or other anatomical landmark, withdraws the stent delivery system, advances a balloon catheter to the stent, attempts to position the balloon catheter marker bands in proper relation to the stent using the stent marker bands and anatomical landmarks as references, and dilates the stent.

On occasion, it may be difficult for the cardiologist to determine where the catheter or balloon is positioned in relation to the stent. For example, some self-expanding stents may be difficult to locate because they may shorten when deployed and, thus, their initial relation to the anatomical landmarks is altered when deployed. Another reason stents may be difficult to locate is because parallax may occur when viewing the body lumen, balloon, and stent on a monitor.

Various catheters, balloon catheters, implantable devices, stents, and markers are commercially available and known in the art. Catheters and balloon catheters are, for example, disclosed in U.S. Patent Nos. 4,762,129; 5,120,323; 5,163,906; 5,232,445; 5,209,729; 5,306,247; 5,403,292; 5,505,699; 5,599,325; and 5,605,543. A device for detecting magnetic resonance signals is disclosed in U.S. Patent Serial No. 08/752,432 filed November 19, 1996.

One attempt to solve the stent locatability problem is to provide a clad composite stent which contains a radiopaque core throughout its length. Such a device is shown in WO 94/16646. Another self-expanding stent, available from Schneider (USA) Inc of Minneapolis, Minnesota, has a radiopaque clad composite structure such as shown in U.S. Patent No. 5,630,840 to Mayer. Also, self-expanding stents can be made of a Titanium Alloy as described in United States Patent Application Serial No. 08/598,751, filed February 8, 1996.

Implantable devices are made of conductive and non-conductive materials known in the art. Self-expanding medical prostheses frequently referred to as stents are well known and commercially available. They are, for example, disclosed generally in the Wallsten U.S. Patent No. 4,655,771, the Wallsten et al. U.S. Patent

No. 5,061,275 and in Hachtman et al., U.S. Patent No. 5,645,559. A bioabsorbable endoprosthesis is, for example, disclosed in J. Stinson's United States Patent Application entitled "Bioabsorbable Self-Expanding Stent", Serial No. 08/904467, filed August 1, 1997. Another bioabsorbable stent is disclosed in J. Stinson's United States Patent Application entitled "Bioabsorbable Implantable Endoprosthesis With Reservoir And Method Of Using Same", Serial No. 08/905,806, filed August 1, 1997.

A radiopaque marker is disclosed in J. Stinson's and Claude Clerc's United States Patent Application entitled "Radiopaque Markers And Methods Of Using Same", Serial No. 08/905,821, filed August 1, 1997. Another marker is disclosed in J. Stinson's United States Patent Application entitled "Bioabsorbable Marker Having Radiopaque Constituents And Method Of Using Same", Serial No. 08/904,951, filed August 1, 1997.

Although a radiopaque stent is an improvement for locatability purposes, the cardiologist must still rely on visual detection of the stent. In addition, radiopaque markers do not solve all of the problems associated with locating implantable devices.

The need for rapid and accurate stent locatability and methods to accomplish the same has particularly become more important with advances in micro-surgery, neuro-surgery, and conventional angioplasty procedures.

Summary of the Invention

Accordingly, there is a need for catheters having implantable device sensing characteristics. The implantable device sensing catheter assists a physician in determining the location of a predetermined portion of a catheter or balloon relative to an implantable device in a body lumen.

Implantable devices are used within body vessels of humans for a variety of medical applications. Reference in this application to implantable devices is generally made to a stent, however, other devices include intravascular stents for treating stenoses, stents for maintaining openings in the urinary, biliary, tracheobronchial, esophageal, and renal tracts, and vena cava filters.

The present invention is preferably used with conductive implantable devices. Such conductive implantable devices may be partially coated or covered with various non-conductive materials. Such non-conductive implantable devices or materials may have exposed conductive areas or conductive marker constituents or portions thereon.

Overall, the implantable device sensing catheter relatively improves the physician's ability to locate and dilate an implantable device in a body lumen. Use of the implantable device sensing catheter may advantageously result in stent dilatation rather than dilatation of adjacent healthy artery.

The signal from the sensors may be forwarded or

transmitted to a microprocessor and to an output device such as a speaker or monitor to advantageously convey information to the physician. With the signal, the physician may be able to determine the location of a predetermined portion of the catheter or balloon relative to an implantable device.

In sum, the invention relates to an implantable device sensing catheter including an elongated tube having at least a portion of a circuit and including at least one sensor. The sensor is disposed on the elongated tube and provides one or more signals to or through the circuit relating the location of a predetermined portion of the elongated tube relative to an implantable device upon contact of the sensor with the implantable device. The implantable device may be a stent. The circuit may further include a conductive path which communicate with the sensors. The sensor and conductive path may be made of materials including metals, conductive paints, conductive epoxies, or conductive polymers. A balloon may be disposed on the elongated tube. The signal may include voltage, resistance, or amperage. The signal may be forwarded to a measurement device including a voltage meter, ohm meter, or amperage meter. The signal may be transmitted to an output device. The output device may be disposed on the catheter. The output device may include a monitor, speaker, computer, or display. The output device may provide a signal, digital signal, video signal, image, audio signal, or combination thereof relating the location of a predetermined portion of the catheter relative to the implantable device. The signal may be transmitted to a microprocessor and converted to an audio or visual signal. The signal may be based on resistance and the amount of resistance measured at an output device may corresponds to the position of the sensor in the implantable device. The resistance value at the output device may correspond with the amount of contact with the sensor. The relationship of resistance and contact may be linear or nonlinear. The implantable device is preferably at least partially conductive or includes one or more conductive constituents disposed thereon. The signal may be forwarded or transmitted to a relay. The relay may be adapted to provide wireless transmission to another device. The circuit and sensor may be at least partially disposed on the balloon.

The invention also relates to an implantable device sensing catheter including an elongated tube having at least one sensor disposed thereon. The sensor communicates one or more signals of information corresponding to the location of a predetermined portion of the elongated tube relative to a implantable device in a body lumen. The sensor communicating one or more signals when the sensor is not in contact with the implantable device, when the sensor makes contact with the implantable device, and when the sensor is substantially disposed in the implantable device.

The invention also relates to an implantable device sensing catheter including an elongated tube having at

least one balloon disposed thereon. The balloon has at least one sensor disposed thereon. The sensor communicates one or more signals of information corresponding to the location of a predetermined portion of the balloon relative to an implantable device in a body lumen. The sensor communicates one or more signals when the sensor is not in contact with the implantable device, when the sensor makes contact with the implantable device, and when the sensor is substantially disposed in the implantable device. The sensor may communicate one or more signals to an output device and the output device may portrays substantially real-time information showing the relationship of the balloon to the implantable device. The output device may portrays substantially real-time information when the balloon is substantially disposed in the implantable device.

The invention also relates to a kit including an output device, an implantable device, and a catheter. The catheter having at least one circuit and sensor disposed thereon. The sensor provides one or more signals relating the location of a predetermined portion of the catheter relative to the implantable device. The implantable device may be a stent. The catheter may further include a balloon having the sensor disposed thereon.

The invention also relates to a method of dilatating a stent including the steps of inserting a stent into a body vessel; inserting a balloon catheter having at least one sensor circuit disposed thereon into the body vessel, the sensor circuit adapted to provide or communicate one or more signals to an output device relating the location of a predetermined portion of the balloon relative to the stent into a body vessel; interpreting the output device information at least once; and manipulating the balloon at least partially within the stent until the output device relates the desired position of the balloon catheter relative to the stent. The method may further include the step of dilatating the balloon at least once.

The invention also relates to an implantable device sensing catheter including an elongated tube having a balloon disposed thereon. The balloon has at least a portion of a circuit disposed thereon for detecting and providing electrical response signals. The circuit includes at least one sensor means disposed on a predetermined portion of the balloon and proximal ends adapted and arranged for interconnection to at least one of a relay, measurement device, microprocessor, or output device. The balloon is adapted to be inserted into a body lumen during a medical procedure using an implantable device. The sensor means is adapted and arranged for exposure to and contact with the implantable device during the medical procedure and to detect and provide one or more electrical signals through the circuit relating the location of the predetermined portion of the balloon relative to the implantable device upon contact of the sensor with the implantable device.

Still other objects and advantages of the present invention and methods of construction of the same will become readily apparent to those skilled in the art from the

following detailed description, wherein only the preferred embodiments are shown and described, simply by way of illustration of the best mode contemplated of carrying out the invention. As will be realized, the invention is capable of other and different embodiments and methods of construction, and its several details are capable of modification in various obvious respects, all without departing from the invention. Accordingly, the drawing and description are to be regarded as illustrative in nature, and not as restrictive.

Brief Description of the Drawings

FIG. 1 is an isometric view of a balloon catheter embodying the present invention approaching a stent; FIG. 2 is an isometric view of another embodiment of the present invention approaching a stent; FIG. 3A is a side view of another embodiment of the present invention approaching a stent; FIG. 3B is a side view of the embodiment in Fig. 3A as the distal shoulder of the balloon contacts the stent; FIG. 3C is a side view of the embodiment in Fig. 3A as the balloon is substantially disposed in the stent; and FIG. 3D is a side view of the embodiment in Fig. 3A as the proximal shoulder of the balloon exits the stent.

Detailed Description of the Invention

FIGS. 1-3 illustrate several embodiments of an implantable device sensing catheter 10 having a balloon 12 disposed on the shaft 17 with one or more sensors 14 disposed on the balloon 12.

The sensing catheters 10 in FIGS. 1-3 are illustrated outside of a body lumen and in a substantially expanded state. In practice, the balloon 12 will be in a deflated state or in a minimally inflated state and inside a body lumen when the balloon 12 enters the stent 20.

The catheter 10 may be provided with the sensors 14 positioned on the catheter 10 and without a balloon 12. The sensors 14 may be continuous or individual separate units or circuits. For either system, a signal may occur upon contact of the sensor 14 with the stent 20 during longitudinal or radial movement of the sensor 14, expansion of the balloon 12, or a combination thereof. Contact between the sensor 14 and the stent 20 will generally occur at the proximal edge of the stent 20 or at the inside surface of the stent 20.

The sensors 14 may be arranged on the catheter 10 or balloon 12 in predetermined patterns including longitudinal, circumferential, helical, curved, angular patterns, or combinations thereof. For example, circumferential-shaped or U-shaped sensors 14 disposed on the balloon 12 may be used to correlate and define the position of the balloon 12 in relation to the stent 20.

The sensors 14 may be thermally, adhesively, or

chemically disposed to the catheter 10 or balloon 12. The sensors 14 are further connected to a conductive path 16 which conducts or carries signals from the sensor 14 to a connection 22 and then to a relay 25, measurement device 30, microprocessor 40, or output device 50.

Typically, the sensors 14 are disposed on the balloon 12 surface and connected to a conductive path 16. The conductive path 16 is connected to a connection 22 which runs through a wall 19 in the catheter shaft 17. The connection 22 is further connected, for example, to a wire or conductive path 16 which runs along the catheter shaft 17 to the relay 25, measurement device 30, microprocessor 40 or output device 50. One or more epoxy connections 22 including an epoxy-filled hole may be incorporated in the shaft 17 and circuit to make the electrical or conductive connections between the components of the system.

The sensors 14, conductive path 16, and connection 22 may be made of a conductive wire, conductive paint, conductive polymer, vapor deposited metal, conductive coatings, conductive film, conductive epoxy, conductive metals, or other comparable conductive materials known in the art adaptable to carry an electrical signal. The sensors 14 and conductive path 16 may be made of the same material and disposed on the balloon 12 or catheter 10 using the same methods. The sensors 14 may be made of a material having greater resistance than the conductive path 16. For example, the shaft wires may be made of a low resistance wires such as copper and the sensor 14 may be made of conductive paint which has much more resistance than the shaft wires. The conductive path 16 may be conductive paint or conductive polymer which extends down the length of the catheter shaft 17. The sensor 14 may have a resistance in the range of about 50 Ω (ohms) to about 2 K Ω (ohms). The sensor 14 or conductive path 16 may be made of materials having a resistance greater than 500 Ω (ohms) and up to 200 K Ω (kilo-ohms).

The conductive path 16 may connect to a measurement device 30 such as an ohmmeter, voltage meter, or amperage meter. The ohmmeter may be connected to a microprocessor 40 that converts the signal to an audio signal, a video signal or image. The sensor circuit may include a microprocessor 40 programmed to output a signal to an output device 50. The output device 50 may be any type of messaging medium including monitor, meter, speaker, indicator, imaging system, or display that provides an image, or some quantifiable information or measurement. The measurement device 30 may be the output device 50. An output device 50 may be disposed on the proximal end of the catheter 10 to provide a reading of the balloon 12 / stent 20 relative locations. For example, a movable indicator signifying the balloon 12 may be used in a fixed dial having an image of the stent 20. As the balloon 12 is disposed in the stent 20, the output device 50 shows their relative relationship and, accordingly, is advantageously understandable in

most any language.

A relay 25 may be incorporated in the circuit to forward the signal to at least one of the measurement device 30, microprocessor device 40, or output device 50. The relay 25 may be adapted to make a wireless transmission of the signal. The microprocessor 40 may be programmed to calculate the location of the sensor 14 and balloon 12 relative to the stent 20 or to a particular region within the stent 20.

Typically, the signals from the sensors 14 are based on resistance, voltage or amperage. Signals may be forwarded from the measurement device 30 to a microprocessor 40 for further signal processing and thereafter forwarded to an output device 50. Signals may be forwarded to the microprocessor 40 prior to transmission to the devices 30, 50.

The signal may be, for example, an on-off or variable signal depending on the amount of contact between the sensor 14 and the stent 20. The signal may be dependent on the area of contact or a function of resistance of the sensor 14 with the stent 20. The sensors 14 may have various longitudinal lengths, various areas, and resistance in order to provide a variety of signals to a user.

The conductive path 16 may be thermally, adhesively, or chemically connected to the balloon 12 or catheter 10 and, for example, be soldered to the relay 25 which may be disposed on or in a portion of the catheter 10. Alternatively, the relay 25 may be external to the catheter 10. One or more conductive paths 16 may be extruded in the catheter wall 19 or may run as a bundle in a lumen, inflation lumen, or channel inside or outside the catheter shaft 17. The sensor 14 or conductive path 16, for example, may be made of a low resistance material such as copper.

In use, a first signal may be produced and forwarded to the measurement device 30, microprocessor 40, or output device 50 when the balloon 14 is away from the stent 20. One or more additional signals may be produced when the balloon 12 is at least partially disposed in the stent 20, or upon contact between the stent 20 and the sensors 14. The frequency of signals is dependent on the needs of the user.

In Fig. 1, two sensors 14 are arranged and disposed in predetermined patterns, for example, generally parallel and circumferential positions, around a balloon 12. The sensors 14 are preferably located at the shoulders of the balloon 12, but many variations are possible. In use, the sensor 14 may communicate a first signal to an output device 50 which in turn provides, for example, a first reading of zero corresponding to no contact between the sensors 14 and the stent 20; a second signal and reading may correspond to contact of the distal most sensor 14 on the balloon 12 and the stent 20; and a third signal and reading may correspond to contact of both sensors 14 and the stent 20, i.e., both sensors 14 are at least partially disposed inside the stent 20 and contact has been made with the inside surface 21 of the

stent 20. Overall, a variety of signals from the output device 50 may advantageously be generated for the user.

In practice, the balloon 12 may be directed distally in the body lumen to the deployed stent 20, and partially inflated to a low pressure. A signal or reading at the measurement device 30 or output device 50 may indicate that the balloon 12 is at least partially disposed within the stent 20. The signal may be an audio or visual signal communicating the relation of the catheter 10 or balloon 14 to the stent 20. The physician will determine when the balloon 12 and stent 20 are in the desired relationship.

In use, the stent 20 may short out one or more of the sensors 14 upon contact with the conductive component of the implantable device and communicate a corresponding signal to the measurement device 30, microprocessor 40, or output device 50.

FIG. 2 illustrates a catheter 10 with a U-shaped sensors 14 disposed on the balloon 12. In use, when the stent 20 is outside the balloon 12, the circumferential loops of the sensor 14 may have a full resistance of, for example, a value 2X. When the stent 20 is over the distal end 12a or proximal end 12b of the balloon 12 and contact is made between the sensors 14 and the stent 20, the stent 20 wires may short out the distal loop of the sensor 14 and the sensor 14 may have a resistance of, for example, a value X. Similarly, when the stent 20 is over the proximal end 12b of the balloon 12, the stent 20 wires may short out the proximal loop of the sensor 14 and the sensor 14 may have a resistance of, for example, a value X. When the stent 20 is substantially disposed over the balloon 12 and preferably centered, the stent 20 shorts out both loops of the sensors 14 and the sensor 14 may have a resistance of, for example, a value zero. The resistance measurements at the output device 50 would correspond or correlate to an equivalent location of the balloon 12 in relation to the stent 20.

The resistance value and balloon 12 / stent 20 location relationship may be linear. For example, for a single longitudinal sensor 14 disposed on the balloon, the further the balloon 12 is disposed in the stent 20 and makes contact with the stent 20, the sensor 14 has a resistance that is correspondingly lower.

Reference is made to FIGS. 3A-D which illustrate use of the sensing catheter 10, specifically, progressive insertion of the distal portion 12a of the balloon 12 having one or more sensors 14 entering into the interior region of a stent 20. Typically, as the balloon 14 approaches the stent 20, a corresponding output from the measurement device 30, such as an ohmmeter, relates the position of the balloon 12 in relation to the stent 20.

The sensors 14 may be arranged such that the ohmmeter may display a high resistance or first signal when the stent 20 is not overlapping the balloon 12; a medium resistance or second signal when the stent 20 is partially overlapping the balloon 12; and a low resistance or third signal when the stent 20 is fully overlapping the balloon

12.

In another embodiment, a kit for locating implantable devices may include an implantable device sensing catheter 10 having a balloon 12 with sensors 14, and an output device 50.

A preferred method of dilatating a stent 20 includes the steps of inserting a stent 20 into a body vessel, inserting a catheter 10 having a balloon 12 and at least one sensor 14 adapted to produce one or more signals and forward the signals to a device 30, 50 for relating the location of a predetermined portion of the balloon 12 relative to the stent 20, interpreting the output device 50 information at least once, manipulating the balloon 12 at least partially within the stent until the device 30, 50 relates the desired position of the balloon 12 relative to the stent 20, and dilatating the balloon 12 at least once. The method for locating a stent 20 may include steps of watching a visual display or listening for an audible signal which informs the cardiologist as to when the balloon 12 is properly positioned. The method of positioning the balloon 12 may include partial inflation of the balloon 12 or positioning the balloon 12 while deflated.

Another variation of the above method may include the step of interpreting the output device information at least once until the output device indicates that the dilatation balloon 12 is at least partially disposed or substantially disposed in the stent 20. Also, one of the above steps may include use of a microprocessor 40 to calculate an audio or visual signal for the monitor or speaker.

It will be evident from considerations of the foregoing that the implantable device sensing may be constructed using a number of methods and materials, in a wide variety of sizes and styles for the greater efficiency and convenience of a user.

The above described embodiments of the invention are merely descriptive of its principles and are not to be considered limiting.

Claims

1. An implantable device sensing catheter comprising: an elongated tube (17) having at least a portion of a circuit and including at least one sensor (14), the sensor (14) disposed on the elongated tube (17) and adapted to provide one or more signals through the circuit relating the location of a predetermined portion of the elongated tube (17) relative to an implantable device upon contact of the sensor (14) with the implantable device.
2. The implantable device sensing catheter of claim 1 wherein the implantable device is a stent.
3. The implantable device sensing catheter of claim 1 or claim 2 wherein the circuit comprises a conductive path (16) which communicates with the sensors (14).

4. The implantable device sensing catheter of claim 3 wherein the sensor (14) and conductive path (16) are made of materials comprising metals, conductive paints, conductive epoxies, or conductive polymers.

5. The implantable device sensing catheter of any preceding claim wherein the signal comprises voltage, resistance, or amperage.

6. The implantable device sensing catheter of any preceding claim wherein the signal is forwarded to a measurement device (30) selected from the group consisting of a voltage meter, ohm meter, and amperage meter.

7. The implantable device sensing catheter of any preceding claim wherein the signal is transmitted to an output device (50).

8. The implantable device sensing catheter of any preceding claim wherein the signal is transmitted to a microprocessor (40) and converted to an audio or visual signal.

9. The implantable device sensing catheter of any preceding claim wherein the signal is based on resistance and wherein the amount of resistance measured at an output device corresponds to the position of the sensor (14) in the implantable device.

10. The implantable device sensing catheter of any preceding claim wherein the signal is forwarded or transmitted to a relay (25).

11. An implantable device sensing catheter comprising: an elongated tube (17) having at least one balloon (12) disposed thereon, the sensor (14) having at least one sensor (14) disposed thereon, the sensor (14) adapted to detect and communicate one or more signals of information corresponding to the location of a predetermined portion of the balloon (12) relative to an implantable device in a body lumen wherein the sensor (14) communicates one or more signals when the sensor (14) is not in contact with the implantable device, when the sensor (14) makes contact with the implantable device, and when the sensor (14) is substantially disposed in the implantable device.

12. An implantable device sensing catheter comprising: an elongated tube (17) comprising a balloon (12) disposed thereon, the balloon (12) having at least a portion of a circuit disposed thereon for detecting and providing electrical response signals, the circuit including at least one sensor means disposed on a predetermined portion of the balloon (12) and proximal ends adapted and arranged for

int rconnection to at least one of a relay (25), measurement device (30), microprocessor (40), or output device (50), the balloon (12) adapted to be inserted into a body lumen during a medical procedure using an implantable device wherein the sensor means is adapted and arranged for exposure to and contact with the implantable device during the medical procedure and to detect and provide or more electrical signals through the circuit relating the location of the predetermined portion of the balloon (12) relative to the implantable device upon contact of the sensor with the implantable device.

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FIG-1

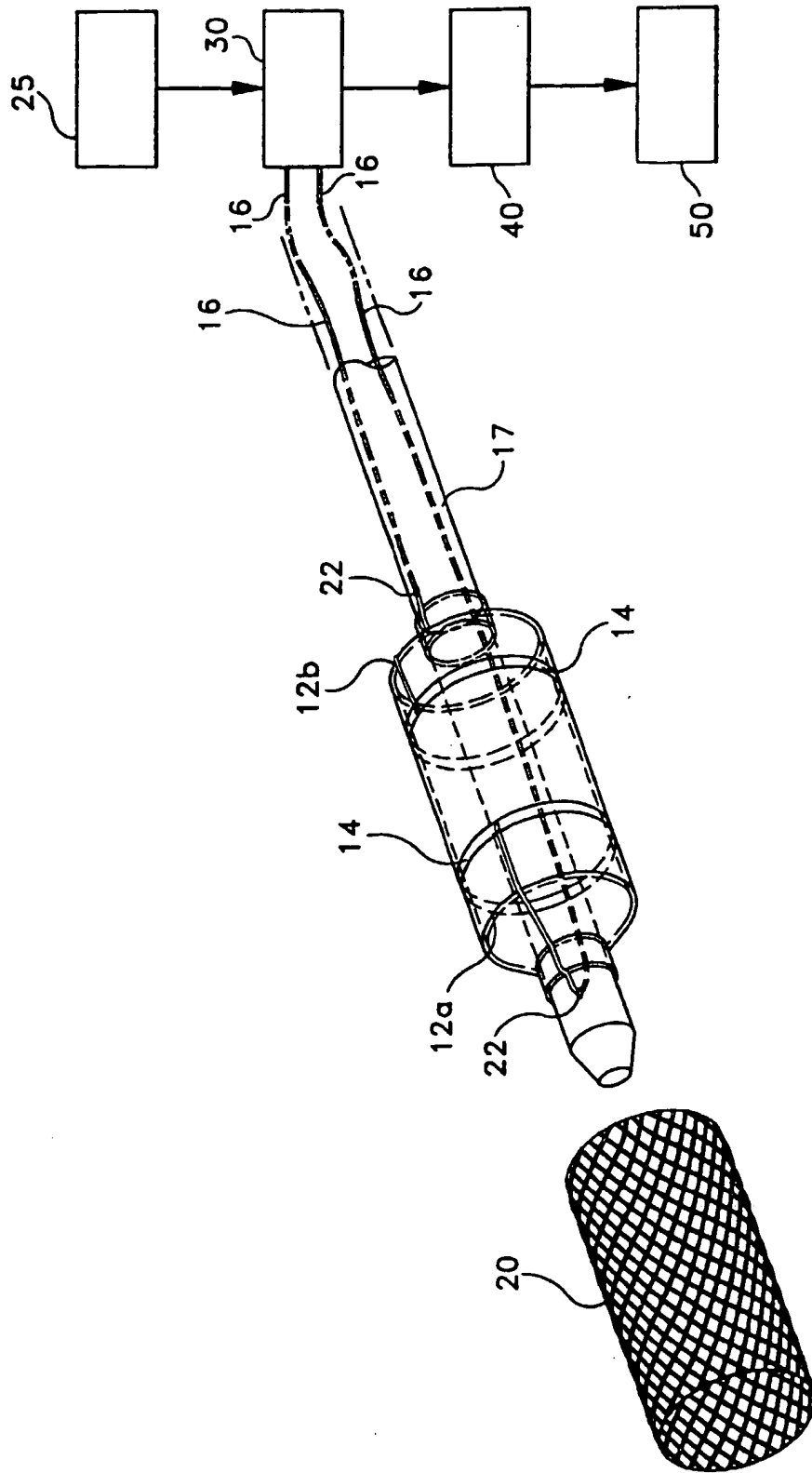


FIG-2

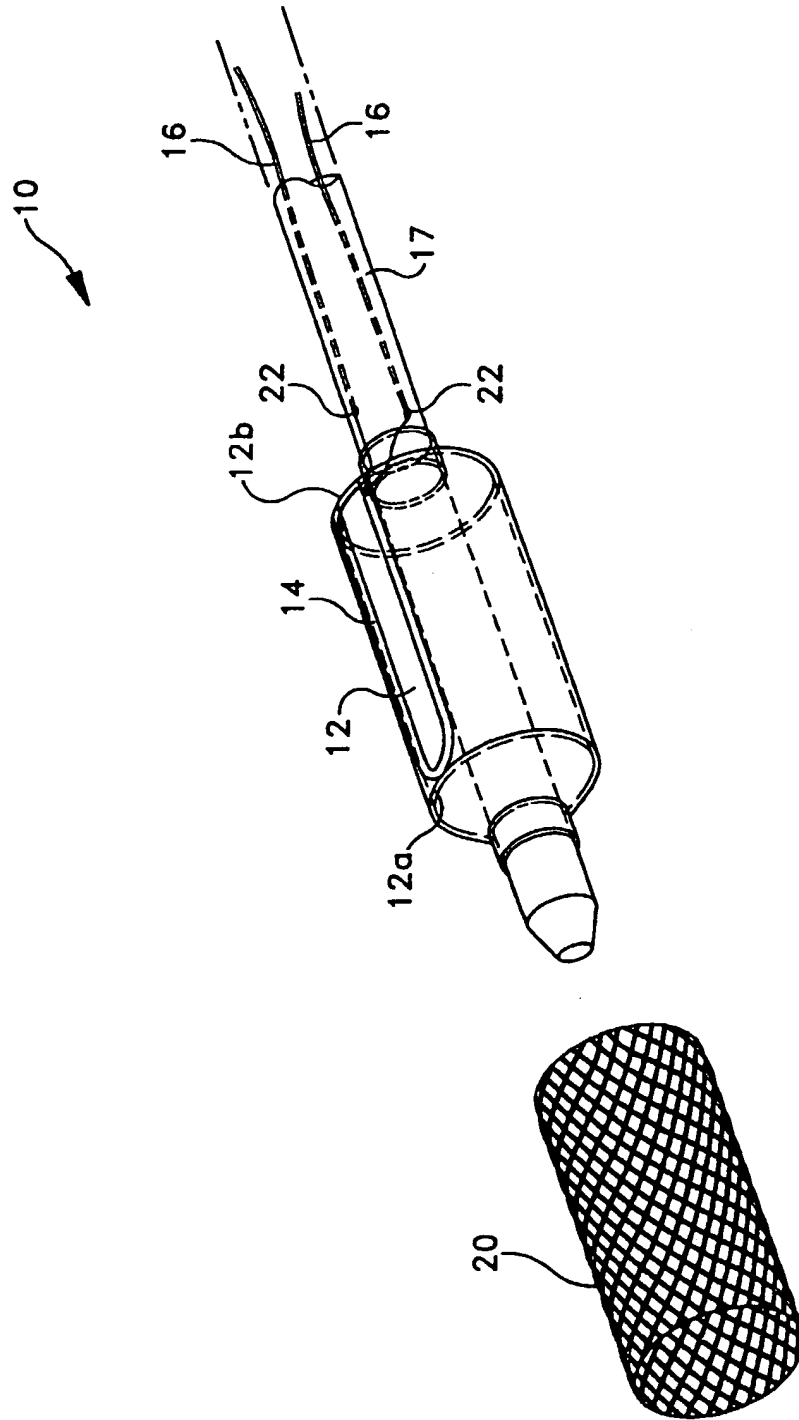


FIG-3A

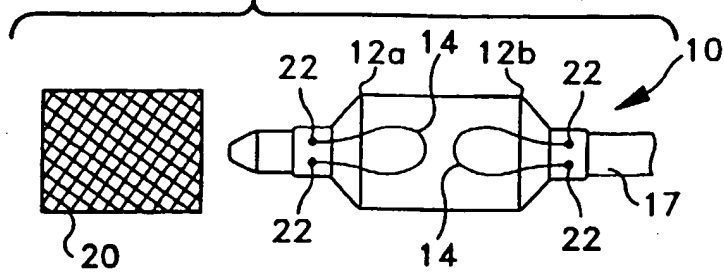


FIG-3B

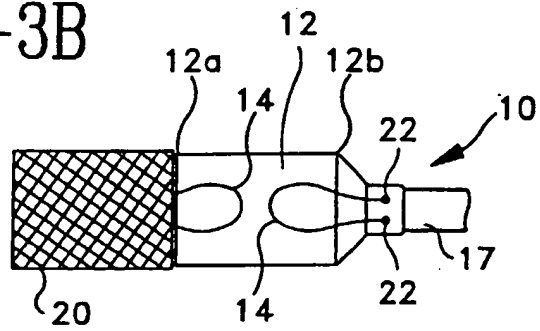


FIG-3C

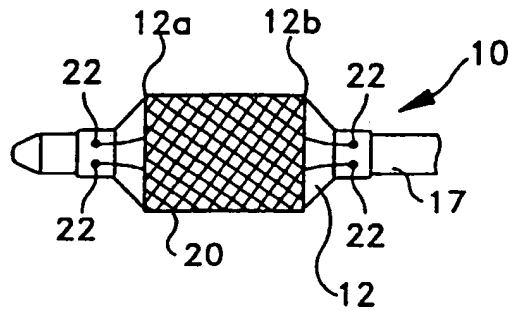
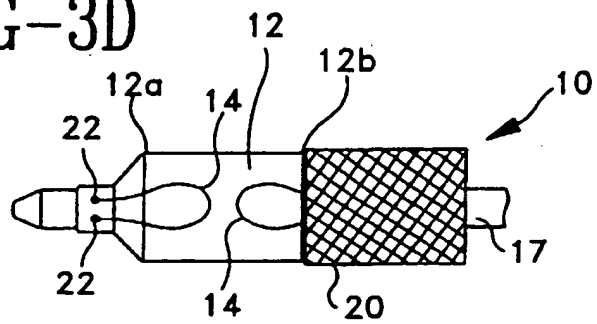


FIG-3D





European Patent
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EUROPEAN SEARCH REPORT

Application Number
EP 97 30 9898

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
P,X	WO 97 32545 A (SCIMED) * the whole document *	1-12	A61M25/00 A61F2/06 A61B5/06
X	DE 39 00 178 A (LUNKENHEIMER) * column 4; figure 1 *	1-12	
X	US 4 304 239 A (PERLIN) * the whole document *	1-12	
X	EP 0 545 739 A (KAJIWARA) * the whole document *	1-12	
X	US 4 522 205 A (TAYLOR) * the whole document *	1-12	
X	WO 94 24931 A (ARROW) * abstract; figure 1A *	1-10	
A	US 5 411 016 A (KUME) * column 1, line 45 - line 61; figure 1 *	1,11,12	
A	US 4 526 177 A (RUDY)		TECHNICAL FIELDS SEARCHED (Int.Cl.6) A61F A61B
The present search report has been drawn up for all claims			
Place of search THE HAGUE		Date of completion of the search 26 March 1998	Examiner Barton, S
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